REMARKS

New claims 20 and 21 have been added to be directed to the provisionally elected peptide.

It is submitted that none of the above amendments are new matter and their entry is requested.

A substitute Sequence Listing has been provided to add a sequence identifier, i.e., SEQ ID NO:26, for the provisionally elected amino acid sequence which corresponds to κ-PVIIA. The provisionally elected sequence is SEQ ID NO:1 in which Xaa_1 is Arg, Xaa_2 is hydroxy-Pro (Hyp), Xaa_3 is Lys, Xaa_4 is Phe, and Xaa_5 is His. The substitute Sequence Listing has also been updated to include the present application information. A computer readable form of the substitute Sequence Listing is submitted with a Statement Pursuant to 37 C.F.R. § 1.821(f). No new matter is introduced by this substitute Sequence Listing.

In the Office Action mailed 13 July 2004, the Examiner restricted the claims with respect to one amino acid sequence recited in claim 1 or 10. As the peptide with one amino acid sequence, Applicants provisionally elect the peptide κ-PVIIA having an amino acid sequence set forth in SEQ ID NO:26. Claims 1-8, 10-17 and 20-21 read on peptide κ-PVIIA . This election of a single single amino acid sequence is made with traverse.

The presently claimed peptides are either (i) a generic formula (i.e., SEQ ID NO:1) for κ-PVIIA which encompasses the sequence for κ-PVIIA or (ii) an analog of κ-PVIIA having specified sequences. Thus, all of the claimed peptides are related to a single peptide, namely κ-PVIIA. According to the claims, all of the peptides have the same activity, namely, treating disorders associated with radical depolarization of excitable membranes by activating a K_{ATP} channel which includes cardiac ischemia, cerebral ischemia, asthma and occular ischemia. These peptides all produce the same effect in the method of treatment, that is, they all treat the specified disorders. The Examiner has not provided any evidence that these peptides, based on a single peptide, do not have the same effect in the claimed methods.

The Examiner makes the claim that each sequence requires a separate search, in reasoning why the sequences were patentably distinct. Applicants assert that this is only a result of the limitations in programming of the search engines. There are chemical species of a core peptidic genus. Nothing prevents one skilled in the art from writing a program that would search the peptidic chemical genus as presently exists for the more traditional chemical genus. This lack of programming is due only to the way a skilled artisan would think about peptide chemicals (letter abbreviations, etc.).

Furthermore, there are two criteria for a proper requirement for restriction between patentably distinct inventions: 1) The inventions must be independent or distinct as claimed; and 2) There must be a serious burden on the Examiner if restriction is not required. See MPEP § 803. Examiners must provide reasons and/or examples to support conclusions. For purposes of the initial requirement, a serious burden on the Examiner may be *prima facie* shown if the Examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant. Insofar as the criteria for restriction practice relating to Markush-type claims is concerned, the criteria are set forth in MPEP § 803.02. See MPEP § 803. If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the Examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the Examiner will not require restriction. See MPEP § 803.02.

Applicants agree that the various peptides may be distinct from each other, but only to the extent of a particular amino acid sequence. However, as stated in the MPEP, as discussed above, distinctness alone is not enough to require a restriction. There must also be a serious burden upon the examiner. In the absence of such a burden, the examiner must examine all of the claims (or in this case, it is urged that all of the peptide claims should be examined). It is urged that the burden of examining all of the peptides of the present application is not a serious one, and that the burden of examining all of the peptides is only slightly greater than examining one of the groups of claims.

The examination entails various aspects. First is a decision concerning utility under 35 U.S.C. §101. Although each peptide species being claimed is distinct, they are all related in their structure and biological activity, as already noted because they are all related to the peptide κ-PVIIA. Consequently, a decision concerning utility will be identical for all of the species, and there is no added burden of examining all of the species as compared to examining only a single species.

The second aspect of examination is whether the provisions of the various paragraphs of 35 U.S.C. § 112 have been met. In general, and in this case, this means reviewing the application and claims for compliance with the provisions of paragraphs 1 and 2 of § 112. As for the enablement aspect as found in paragraph 1 of § 112, all of the peptides are related in their structure and biological activity, as already noted because they are all related to the peptide κ-PVIIA. Since no basis for distinguishing between the enablement of one species vs. another species has been set forth, it is presumed that all of the listed peptides will be treated equally. Again, this means that only a single decision needs to be made concerning all of the peptides. Therefore, this aspect of the examination will not be a serious burden if all peptides are examined, vs. only one of the peptides.

Concerning paragraph 2 of § 112, this involves the wording of the claims. The wording of the claims in each group of claims is identical except for the specified peptide. Consequently, any objections to the language of the claims for one Group of claims is equally applicable to the other Groups of claims. Therefore there is no increase in the burden concerning 35 U.S.C. § 112, second paragraph, if all peptides are examined.

The third aspect of examination is a review of prior art to determine whether the claims are anticipated or obvious. There are two aspects of such a search. A first aspect is a review of the prior art literature and patents. The literature to be reviewed will be identical for all of the peptides. All of the claimed peptides have similar, though not identical, structures and all are claimed to have the same utility. The Examiner has not stated that a search of the scientific literature will be any different for one peptide than for any other peptide. Consequently, the search of the patent literature will clearly be the same for all of the peptides. Because the search of the scientific literature and patent literature will be identical for all of the peptides, there is no added burden concerning this

aspect if all of the peptides are examined. Furthermore, the search will probably entail a computer search based on the peptide sequences in the sequence listing. It is believed that such a search would identify prior art directed to the claimed peptides or peptides having the specified substitutions.

Consequently, it is submitted that the only reason for restriction is that the peptides are distinct from each other. But as explicitly stated in MPEP § 803, the inventions must be distinct and there must be a serious burden on the examiner. MPEP § 803.02 states that if a search and examination of an entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. As urged above, it is asserted that examination of all of the peptides will not impose a serious burden.

In addition, it is submitted that the computer search for the peptide κ-PVIIA will also identify any prior art disclosing analogs (part (b) of claims 1 and 10) or derivatives (claims 9 and 18) of the peptide κ-PVIIA. Consequently no additional searching is required to examine the analogs and derivatives with the corresponding peptide κ-PVIIA , and thus no undue burden exists in this instance.

In view of the above arguments, it is requested that the restriction requirement imposed in the Office Action mailed 13 July 2004 with respect to individual peptides be reconsidered and that all of the peptides be examined together.

Respectfully submitted,

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SEQUENCE LISTING

Please substitute the attached pages 1-8 of Sequence Listing submitted herewith for the eight (8) pages of sequence listing originally filed with the application.